SEA 080846 No Summons Issued

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA, ex *rel.* by AARON CHUNG

Plaintiff,

vs.

DUSA PHARMACEUTICALS, INC., a New Jersey Corporation,

Defendant.

NO. 16-CV-1614 JLR

COMPLAINT AND JURY DEMAND

Filed Under Seal
pursuant to
31 U.S.C. §3730(b)(2)

COMES NOW the United States of America, by and through Aaron Chung, qui tam as Relator, and for a cause of action alleges as follows:

I. NATURE OF THE ALLEGATIONS

A. Levulan is a drug determined by the Food and Drug Administration to be effective at treating actinic keratosis, a pre-cancerous skin condition, on the face and scalp using a treatment protocol. The protocol involves a multi-hour "incubation" period between application and activation by a medical device called a BLU-U Blue Light Photodynamic Therapy Illuminator. It is also approved for use on specific sites where there is actinic keratosis, not for broad area application.

B. Defendant Dusa Pharmaceuticals has promoted the use of Levulan, including the Levulan Kerastick and BLU-U activator, as if they had been approved for short incubation

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times, without the BLU-U activator, for broad areas, and/or on parts of the body other than the face and scalp. It encourages omission of the treatment location from billing records so that non-approved treatments will be paid for by the government. It also promotes unapproved cooling devices for use with the BLU-U product, which increases patient comfort but decreases efficacy. Treatments by other than the delayed application protocol, treatments using the cooling device, broad treatment areas, and treatments on parts of the body other than face and scalp, have not been approved by the Food and Drug Administration.

C. Dusa also gives out large numbers of samples of the Levulan Kerastick to physicians for free in a scheme to keep the Wholesale Acquisition Cost higher so that medicare billing is higher. The product samples are not intended to be given to patients for their own use, free of charge. Rather, the samples are intended to be used in treatment demonstrations and trainings; however, in 2013 there were nearly 4,500 samples given out with under 300,000 units sold, affecting price calculations up to 1.5%. Dusa is causing physicians to bill for free samples and for services provided while using free samples, as well as fraudulently raising the reimbursement price.

D. Defendant Dusa colluded with Foundation Care to become the sole retail distributor of Levulan Kerastick and the BLU-U activator in order to raise prices beyond a reasonable market rate.

E. Through these schemes and others, Dusa is causing healthcare providers to improperly use Levulan and the associated BLU-U medical devices, and consequently to submit false claims to Medicare, Medicaid and TRICARE for federal reimbursement for the "off label" use of the drug and device, and for associated healthcare provider treatment services. Relator Chung claims fraud against the government in violation of the False Claims Act, and on information and belief, this fraudulent scheme continues today.

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F. Defendant Dusa also provides healthcare providers with gifts, payments, and other forms of remuneration to induce them to purchase and recommend and use Levulan and BLU-U on their patients, violating the Sunshine Act, including providing at least one device for free which is used in billing at a local Seattle-area hospital, and giving gifts of meals and other services without tracking them and/or in excess of the allowable limits.

G. Relator is a former employee of Dusa with personal knowledge of some or all of the allegations herein. Under pressure from his manager, he initially promoted off label sales for some years, until approximately April, 2014. Relator's manager used him as a trainer, and his sales were among the highest of the approximately 55 sales representatives (also called "Territory Managers"). In 2014, he became concerned that off label sales were improper and made clear that he would no longer promote them. After he made clear he would not promote off label sales, his employment was terminated for pretextual reasons, specifically based on prior events about which management had known at the time without action. Plaintiff claims retaliatory termination.

I. JURISDICTION and VENUE

1.1 Jurisdiction exists pursuant to 31 U.S.C. §3730(b)(1) and 31 U.S.C. §3732 in that this action seeks remedies on behalf of the United States of America for violations of 31 U.S.C. §3729 by the Defendants.

1.2 The "allegations or transactions" upon which this suit is based have not been publicly disclosed in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit or investigation, or from the news media. 31 U.S.C. 3730(e)(4)(A).

1.3 Knowledge obtained by the U.S. Government was the result of a disclosure made by the Relator.

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1.4 The *qui tam* Plaintiff is an original source in that he "has direct and independent knowledge of the information on which the allegations are based." 31 U.S.C. §3730(e)(4)(B). He has been providing information through this litigation and previously offered to provide information to agents of the United States Government in connection with this matter.

1.5 Dusa Pharmaceuticals, Inc. ("DUSA") is a New Jersey Corporation which transacts business in Seattle, Washington, within the Western District of Washington.

1.6 Venue exists in this District pursuant to 31 U.S.C. §3730(b)(1) in that Defendants are qualified to do business in the State of Washington and transact substantial business in the District.

II. PARTIES

2.1 The Defendant DUSA Pharmaceuticals, Inc., is a New Jersey Corporation with its principal place of business in Massachusetts, and is engaged in the business of, *inter alia*, selling a skin cancer treatment drug called "Levulan" or "Levulan Kerastick" and medical devices to facilitate treatment, including the BLU-U Blue Light Photodynamic Therapy ("BLU-U PDT") Illuminator.

2.2 Relator Aaron Chung resides in the Western District of Washington. He is a former employee of DUSA, and was at material times employed in the capacity of a sales representative, including as Territory Manger, Regional Field Trainer, and interim Regional Sales Manager.

III. STATEMENT OF FACTS

3.1 The practices identified herein have been ongoing for many years. References to the present herein may include current and/or past practices, including the possibility that some practices may have been discontinued over time, including following Relator Chung's retaliatory termination.

A. Medicare Regulations Limit Amounts and Types of Payments for Services

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3.2 Medicare, Medicaid and TRICARE ("the government") pay certain limited fees for services provided to qualified patients. The regulations and policies of the United States Department of Health and Human Services and laws of the various states mandate that federal funds may be paid to health care providers for services provided to qualified patients, but only in certain amounts for certain services.

3.3 As an example of the foregoing regulations and policies, the government pays for products and associated services which have been approved by the Food and Drug Administration. It does not intentionally pay for products or services which have not been approved.

3.4 When physicians submit billings for "off-label" uses without indicating such uses are "off-label," the physicians are submitting false billings as that term is defined in the False Claims Act. When pharmaceutical companies and medical device companies promote such "off-label" sales, they cause physicians to file or submit False Claims as that term is defined in the False Claims Act.

3.5 The Food and Drug Administration has approved "on-label" use of Levulan, including specifically the "Kerastick" formation of Levulan, for treatment of actinic keratosis, a skin condition, on the scalp and face only. The approved treatment protocol involves application of Levulan to the treatment area, an "incubation" period of 12-14 hours for the drug to be absorbed by the skin, and activation of the drug by application of blue light emitted by the BLU-U Blue Light Photodynamic Therapy Illuminator ("BLU-U PDT device").

3.6 Shorter delays between application of Levulan and activation with blue light have not been approved by the FDA. Treatment on other parts of the body has also not been approved, nor have broad area treatments not focused directly on known actinic keratosis lesions. Cooling devices for the skin have not been approved. Treatment with an Intense Pulse Light ("IPL"), or other light than specific wavelength blue light has not been approved.

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3.7 DUSA sells Levulan Kerastick and the BLU-U PDT device to physicians who charge the government for the above-referenced actinic keratosis treatment through DHHS programs including Medicare and Medicaid, TRICARE, and the Department of Defense.

3.8 Actinic keratosis is common in older adults, because it takes years to develop. Many or most treatments for actinic keratosis occur in elderly patients on Medicare.

B. Defendant Engaged in Promotion of non-FDA-approved treatment protocols

3.9 Relator Chung became employed by DUSA on or about February 4, 2008, as a Territory Manager for a five state area including Seattle, Washington. He was promoted in approximately April of 2011 to Senior Territory Manager. His employment was terminated on or about February 25, 2015.

3.10 His supervisor, until mid-2014 was Western Region Sales Manager Anthony Dingolo. DUSA, through Mr. Dingolo and others, trained Mr. Chung in sales and encouraged the promotion of off-label sales for years. Mr. Dingolo employed Mr. Chung as a trainer for other Territory Managers. Initially, Mr. Chung was unaware that the method he had learned from DUSA and was teaching was improper or illegal.

3.11 As DUSA became more cautious about off-label promotion by employees, it hired contractors, including Ms. Kim Gooden, a practice manager then living in Atlanta, Georgia, to communicate with customers and Territory Managers to promote off-label sales. Ms. Gooden developed and distributed sales materials promoting off-label uses.

3.12 Ms. Gooden's materials promoted treatment incubation of "one hour on the face and up to 3 hours [on] the body." She promoted unapproved treatment for acne with a limitation indicating "not covered by insurance," and for "photorejuvenation" and actinic keratosis without that limitation. She promoted treatment "using IPL as activator" for Levulan, instead of blue light.

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3.13 Similarly, materials distributed by DUSA to salespeople and managers (including at a January, 2010 sales meeting in St. Louis) explicitly promoted shorter incubation periods than approved by the FDA, and included lists of incubation periods varying by body parts other than face and scalp.

3.14 None of these treatment variations were approved by the FDA.

3.15 Nevertheless Mr. Dingolo told Mr. Chung that their physician customers know that "skin is skin," and that if the product is effective for face and scalp treatment, it will be at least somewhat effective on thicker skin in other locations. Mr. Dingolo told Mr. Chung and others that they could sell many more Kerasticks by promoting their use on unapproved areas of the body.

3.16 In order to promote greater sales by DUSA, Mr. Dingolo told Mr. Chung to encourage physicians to treat on other areas of the body, but to caution customers to bill without identifying the location of the lesion in the billing record.

3.17 Mr. Dingolo also trained Mr. Chung to encourage non-FDA approved treatment protocols, by instructing Mr. Chung how to teach physicians and other sales people through "in service" demonstration events at dermatologists offices and similar locations. Per Mr. Dingolo's instructions, these events would use a volunteer patient and sample Levulan supplied free of charge by DUSA. The training sessions were conducted with short incubation periods. At times, the demonstrations involved other body parts than face and scalp.

3.18 Short absorption periods and areas of treatment other than the face and scalp have not been approved by the FDA, but this is how the "in service" trainings for physicians were conducted. Mr. Dingolo also told Mr. Chung to tell the physicians the company was studying a shorter absorption period.

3.19 Actinic keratosis lesions are specific locations on the skin where cells are growing abnormally, often due to sun exposure. When these lesions grow large enough to be

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observed, Levulan and BLU-U PDT can be applied to the specific site. Site-specific application has been approved by the FDA. The FDA has also not approved field or broad area treatment. DUSA has promoted local area or broad area treatment despite the lack of FDA approval.

3.20 The company had initiated the "BASDI" study ("broad area application and/or short drug incubation") in 2011 for this purpose. Although there were promising results, which DUSA encouraged its sales team to discuss, the FDA did not approve additional protocols. Nevertheless, Mr. Dingolo encouraged Mr. Chung to tell physicians that results were promising and the shorter protocol was effective.

3.21 Some of the materials supplied by DUSA to Mr. Chung and other salespeople include references to off-label promotions, including references to encouraging physicians to use cooling fans. This is because the treatment can be painful for many patients. While cooling the skin reduces pain, it also reduces the effectiveness of the treatment, and is not FDA approved.

3.22 If the product is used as indicated, an effective dose will be absorbed by the precancerous portion of the skin and, when activated, destroy cancer cells effectively. The average patient may need 1-2 treatments per year as more actinic keratosis lesions arise with time. However, if the drug is not given adequate time for absorption, or the skin is cooled, additional treatments are more likely to be necessary, causing additional medical billing.

3.23 The face and scalp are small areas of the body, relative to the back, neck, and arms. If the product is used for larger areas of the body, more product is used, meaning more product is sold to the physicians, and more product and application services are billed to the government.

3.24 Mr. Dingolo's behavior was intentional. For example, Mr. Dingolo led a mandatory regional teleconference call in early 2014 when he specifically asked Portland

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Territory Manager Libby Christensen to teach his regional employees how convince Kaiser Hospitals to treat non-FDA approved body sites.

3.25 Ms. Christensen complied by explaining her methods, which included giving out written information that encouraged non-FDA-approved protocols, and conducting "in service" training demonstrations on non-approved body parts. He repeated this push during a Sales Meeting on February 10 through 11, 2014.

3.26 Mr. Dingolo's encouragement to off label selling for his subordinate Territory Managers was the norm throughout the company, and was repeated not only with his other subordinates outside of Mr. Chung's presence, but by other Regional Sales Managers for their subordinates.

3.27 Mr. Chung made efforts to obtain approval for Levulan use and sale on other body parts than face and scalp. He encouraged the state Medical Association in Montana to seek approval from Noridian (covering the Dakotas, Montana and Wyoming), for areas other than the face and scalp, and was successful, in getting Noridian approval for parts of his personal territory, but not for other parts of Mr. Dingolo's territory where Mr. Chung was a trainer.

3.28 Normally the area to be treated is prepared by washing with soap and water. If there is less skin between the keratosis and the drug, theoretically, more drug could be absorbed rapidly. If the skin is washed with acetone or other solvent, additional skin is removed, and the Levulan would be more rapidly absorbed. For a time, DUSA promoted washing with acetone, even though it was not FDA approved.

3.29 Another Territory Manager was named Jennifer Kasten. Her territory included parts of Arizona. She quit working for DUSA in February, 2014, but was later rehired as Western Region Sales Manager in November, 2014, replacing Mr. Dingolo.

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3.30 After she quit in early 2014, Ms. Kasten was replaced as Territory Manager (salesperson) by Danielle Tames, who was assigned to meet with customers in Arizona. Relator Chung was training Ms. Tames at the Beatrice Keller Clinic in Sun City West (located at 14506 W. Granite Valley Drive, zip code 85375) when the healthcare providers there expressed that Ms. Kasten had promoted off label use of Levulan and the BLU-U PDT device.

3.31 Ms. Kasten promoted Levulan with shorter incubation periods, for broad area treatment (painting the skin widely, not just spot-dosing AK lesions), treatment of areas of the body other than face and scalp, use of skin cooling fans for patient comfort, and promoting billing for the Levulan "samples" received for free with purchases. None of these techniques are FDA approved, but Mr. Chung was told she had promoted them this way in Arizona. She also made gift baskets for offices and staff, which were not reported.

3.32 Additionally, after she was rehired and was Western Region Sales Manager in January, 2015, Ms. Kasten directed the Territory Managers to give out treatment day gift baskets to healthcare providers without tracking the value of the gifts, and to use an unapproved FDA cooling device. Ms. Kasten gave out a protocol sheet to healthcare providers which included her own home-made marketing materials. She also gave out charts on effectiveness of short incubation periods, including some which had been created by Dr. Kevin Crawford and passed out in January of 2010 at a St. Louis sales meeting.

C. Wholesale Acquisition Price Manipulation

3.33 DUSA's pricing policies include giving away samples in connection with purchases. Regional Sales Manager Anthony Dingolo and Regional Sales Manager Jennifer Kasten instructed Mr. Chung and other sales representatives to give physicians one box (containing 6 Kerasticks) of Levulan product samples if they bought six boxes of the product, and two samples boxes if they bought twelve boxes of Levulan. This meant that the actual price was significantly lower than the "per box" price.

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3.34 Using this practice, and others such as giving out samples at demonstrations (which were often billed under the patient name), in 2013 DUSA gave away over 4,400 sample boxes on sales of about 297,000 boxes. Other years showed similar proportions. If the sample boxes were included in the calculation the actual acquisition price would be between 1% and 2% lower.

3.35 DUSA also consistently raised the price of Levulan, sometimes very significantly, effective the first of each year, incentivizing large purchases by physicians at the end of a year. DUSA representatives promised physicians that samples would be given in January if they purchased in December. DUSA representatives informed physicians they could bill for the samples as if they had been purchased from DUSA.

3.36 This is a nationwide practice, under which thousands of boxes of samples are given away in connection with purchases, and is in part intended to inflate the Wholesale Acquisition Price that physicians can charge for the Levulan Kerastick in the following year. Physicians charged the government for boxes that were given to them as samples.

D. Sunshine Act Violations by the Defendants

3.37 The Sunshine Act was effective April 2013, with data collection starting August 2013 and first reporting March, 2014. It requires all gifts and payments to healthcare providers from pharmaceutical companies to be reported publically. DUSA failed to timely implement accurate reporting.

3.38 During January, 2015, Ms. Kasten violated the Sunshine Act during the Winter Clinical Dermatology Meeting at the Grand Hyatt Koloa by hosting an unreported dinner for physicians.

3.39 The value of the dinner violated DUSA internal maximum limits policies.

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3.40 Vice President David Fadness reviewed the expense report in approximately April, 2015. Mr. Chung was treated very differently than Ms. Kasten, and terminated for a similar or less serious violation before the rules had been made clear.

3.41 In February, 2010, Mr. Dingolo wanted to demonstrate a BLU-U device to Virginia Mason Medical Center in Seattle. It was offered for a 90 day period and should have been reported as a gift. The device was never purchased and is still in use at Virginia Mason.

3.42 Mr. Dingolo told Mr. Chung that he did not want them to purchase the machine, but to use the funds to purchase Kerasticks. DUSA representatives was required to report this gift, but failed to do so since 2010.

E. Intentional Ongoing Scheme or Plan

3.43 In April, 2015, Mr. Chung became more concerned that his then-supervisor, Anthony Dingolo, was teaching him and encouraging him to break the law. After a national sales meeting on or about April 20, 2014, Mr. Chung learned that DUSA was ostensibly taking a stronger internal stand against off-label selling. At that time he came to understand more about the practice. He signed agreements not to sell off label, but then shortly thereafter his supervisor, Dingolo, instructed him that his sales goals were increasing.

3.44 Dingolo asked Mr. Chung how he was going to meet his sales goals "if we follow the rules." Specifically that interaction was related to selling for areas of the body other than face and scalp. Mr. Chung responded that under these guidelines, i.e., without off label promotions and encouraging whole-body use by physicians, the sales goes were unattainable. Mr. Chung said "I am not going to get in trouble" for off label selling. Mr. Dingolo responded that Mr. Chung's approach was unacceptable, and soon thereafter demoted him from his Regional Sales Trainer position. He and his co-workers were told they would be fired if they didn't meet the goals, which were unattainable without off-label selling.

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3.45 DUSA was aware that, by raising its sales goals at the same time as it emphasized only on-label selling, it was pushing its sales force to sell off-label despite its claim to allow only on-label selling.

F. Non-Reimbursable Services Were Paid By the Government

3.46 As referenced above, because of the off label selling, healthcare providers are treating patients with protocols not approved by the FDA, and on information and belief, are charging the government for such treatment, both in terms of services provided by physicians off-label, and sales of the Kerastick product.

3.47 Since application to AK lesions on the face and scalp never or rarely requires more than one Kerastick, any billing for more than one stick in a day is likely to be off label.

3.48 Physicians have also billed the government for samples given to them for the in service treatments by DUSA, and for "sample" boxes given out for higher volume purchases, as referenced above. At around $130.00 per stick, 4,000 samples represent over $500,000 billed to insurance and Medicare. Since AK's develop over long periods, many or most treatments are for older patients, many or most of whom are Medicare eligible.

H. These are Fraudulent Misrepresentations

3.49 The purpose of promoting Levulan and the BLU-U PDT units "off label" is to encourage physicians to use them in ways not approved by the FDA. The purpose of encouraging the falsification of the billing records is to obtain monies for DUSA, directly or indirectly, from the United States Government, which monies DUSA would not otherwise obtain.

3.50 The defendants knowingly caused to be presented to an officer or employee of the United States Government, false or fraudulent claims for payment or approval.

3.51 The defendants knowingly caused a false record or statement to be made and/or used in order to get a false or fraudulent claim paid or approved by the Government.

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3.52 The defendants conspired to defraud the Government by getting a false or fraudulent claim allowed or paid.

3.53 The defendants made these false representations of material fact knowingly as that term is defined in 31 U.S.C. § 3729(b).

3.54 The false representations were believed by the government and acted upon by the government to its damage.

3.55 These practices resulted in billing for more products and services than were legally allowed, and resulted in DUSA receiving more money than it was entitled to because it encouraged and trained physicians to bill falsely.

3.56 These fraudulent practices have been ongoing and continuing for a period of years and continued after Mr. Chung's termination.

3.57 DUSA encourages, condones, organizes and requires these fraudulent off label practices and DUSA's practices are part of a pattern and practice of off label selling techniques.

J. Wrongful Retaliatory Termination

3.58 Relator Chung stopped engaging in the above-referenced practice when he learned they were illegal, in part, due to company-wide training in April of 2014. On November 12, 2014, he reported to DUSA Regulatory Compliance Officer Joanne Lavalle that he had, for years, been told to promote off label by former manager Anthony Dingolo. Instead of investigating the allegations Mr. Chung raised against Mr. Dingolo and the company-wide practices he represented, stale accusations against Mr. Chung were re-investigated and used as a pretext for discipline.

3.59 DUSA fired Mr. Chung for allegedly engaging in subsequent promoting off-label selling of Levulan and the BLU-U PDT device for use on the arms and back. Mr. Chung denies the allegations and believes they were leveled as part of a cover-up for his reports and in retaliation for his investigation and opposition to off-label selling.

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3.60 Mr. Chung believes other Territory Managers were not fired for similar behavior.

IV. CLAIMS OF THE UNITED STATES

4.1 The facts stated above give rise to a violation of the Federal False Claims Act, 31 U.S.C. 3729(a)(1)(2)(3).

4.2 The defendants are liable for the actions of their agents, and their employees under the doctrine of Respondeat Superior.

V. DAMAGES SUFFERED BY THE UNITED STATES

5.1 As a proximate cause of the fraudulent practices described above the United States of America has suffered damages in amounts fraudulently billed to the United States.

VI. CLAIMS OF RELATOR CHUNG FOR HIMSELF

6.1 Aaron Chung's employment was terminated because he opposed illegal practices referenced herein. This conduct violates 31 U.S.C. §3730(h). As a separate claim arising out of similar facts, this conduct violates the common law of the State of Washington, specifically the tort of Wrongful Discharge in Violation of Public Policy.

VII. DAMAGES SUFFERED BY RELATOR CHUNG

7.1 As a proximate cause of the fraudulent practices described above Aaron Chung has suffered damages in the form of lost wages, damage to his career (future earning capacity), general damages for emotional distress, and other actual damages.

VIII. PRAYER FOR RELIEF

WHEREFORE plaintiff prays for damages as follows on behalf of the United States, and/or on his own behalf as appropriate:

On behalf of the United States:

8.1 Economic damages in an amount to be proven at time of trial.

8.2 A civil penalty of not less than $5000 and not more than $10,000 per violation.

8.3 Treble damages as provided for in 31 U.S.C. §3729(a).

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On behalf of Aaron Chung:

8.4 Lost wages and benefits of employment, both past and future, lost future earning capacity, and other economic damages in amounts to be proven at time of trial.

8.5 General damages for emotional distress.

8.6 Other actual damages in amounts to be proven at time of trial.

On behalf of either or both the United States and Aaron Chung:

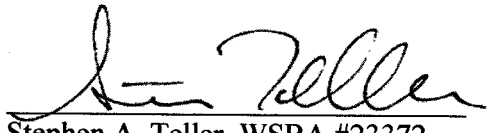
8.7 Prejudgment interest.

8.8 Reasonable attorney fees and costs.

8.9 Whatever additional damages the court shall deem to be just and equitable.

DATED this 22nd day of September, 2016.

Relator hereby demands a Jury



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